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Stenting continues to dominate cardiology

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The stent craze just keeps on growing, accounting for one in ten papers presented at the European Society of Cardiology meeting in Birmingham, UK, reports David Firn.
Stent use has grown dramatically since 1993 when the Benestent and Stress trials proved they really do reduce restenosis. The price for reduced restenosis was increased bleeding, but new pharmacological regimes have overcome this problem to the point that Professor Patrick Serruys of the Rotterdam Thoraxcenter says it is now safer than balloon angioplasty. Stent use accounts for 25-50% of angioplasties at most centres and is as high as 70% at centres of excellence such as the Royal Brompton National Heart and Lung Hospital in London.
There are now around 20 stents available in Europe just two coronary stents in the US, but competition has not yet brought down the price. Some cardiologists are already worried that a cheap copycat design could cause mayhem on the scale of the Bjork-Shiley valve if it failed. Johnson & Johnson had to show that the Palmaz-Schatz stent could stand up to a lifetime on the surface of a beating heart.
Professor Paul Hugenholz has proposed an ESC working group on stent manufacture, implantation and utilisation. The society has not yet approved the move but he hopes that a code for testing new devices and registries of patients will prevent a major medical disaster. He believes new stents should be clinically evaluated in at least 100 patients before they are released and that post-marketing surveillance should include a minimum of 300 patients for at least a year.
He considers guidelines are essential to prevent stagnation of the rapidly evolving stent market when the European Medical Devices Directive becomes mandatory in 1998. Stents will fall into Class III, the group of devices considered to be associated with the highest level of risk.
Cordis unveils Crown stent
Cordis, now part of the Johnson & Johnson empire and incorporating J&J's interventional cardiology business, launched its new Palmaz-Schatz Crown stent at the European Society of Cardiology meeting (August 25th-29th). Like its best-selling predecessor, the model 153, the Crown stent is a slotted stainless steel tube design. However, when expanded, a new, curvaceous diamond cell shape is revealed.
Cordis claims that the new model improves flow, reduces restenosis, minimises acute closure and provides a more stable endoluminal surface. It is also able to penetrate tortuous arteries that were inaccessible to the original Palmaz-Schatz 153 stent. Cordis has eliminated the weak link of the original design, the articulation between the two expandable sections, which is the most likely point for restenosis. Cordis' vice-president of corporate relations, Charles McDowell, says the new stent will be launched throughout Europe - initially with limited production but

eventually including an increasing number of east European countries - towards the end of the year. It will be available in 15, 22 and 30 mm lengths with or without an integral sheath. The stents are mounted on a new rapid-exchange delivery system, PowerGrip, which includes a high-pressure, non-compliant balloon.
Goliath II?
Although the Palmaz-Schatz stent is by far the best selling device, it is not the most flexible. The Crown stent should address this weakness but will face strong competition from an ever increasing armamentarium of coiled wire and multiple ring devices. Not least among these is Cook's second-generation Gianturco-Roubin stent which is in clinical evaluation (see Clinica No 697, p 18).
Professor Jean Marco of the Pasteur Clinic in Toulouse, France, said the new Gianturco-Roubin stent allows treatment of complex, distal lesions in very tortuous vessels. Speaking at a Cook-sponsored symposium, he said restenosis occurred in five out of 16 patients who had completed one-year follow-up angiography. One patient died from cardiac insufficiency and one from cancer. Only one required bypass surgery. There was no subacute thrombosis, death, MI or reintervention in the first three months and the coiled flat-wire structure of the stent prevented damage to arterial side branches.
Dr Antonio Colombo confirmed that residual stenosis is a problem in small vessels, even after high-pressure inflation with oversized balloons. One patient had suffered side branch occlusion in a 34-patient study, he admitted. However, prior attempts to deploy other flexible stents had failed in 11% of lesions in the study group, w